

## REMARKS

Claims 1-5 and 9-11 were pending at the time of the mailing of the outstanding Office Action. By this amendment, claims 9-11 have been cancelled without prejudice or disclaimer as to the subject matter contained therein. Claim 1 has been amended.

In the Office Action of 29 May 2008, the examiner rejected claims 1-4 and 9-11 under 35 U.S.C. § 102(e), as being anticipated by US Application Publication No. 2003/0083646 to Sirhan et al. (hereinafter "Sirhan"). Under 35 U.S.C. § 102(b), the Examiner also rejected claims 1-5 as being anticipated by US Application Publication No. 2002/0055769 to Wang (hereinafter "Wang").

Claim 1 has been amended to further specify that the concentration of the pharmaceutically active substance *in the coating* varies in the longitudinal direction of the stent. Support for this amendment may be found in paragraphs 0035-0036 and 0050-0051. This amendment distinguishes the claims over the cited prior art.

In the Office Action, Sirhan is cited as providing a stent with a coating system comprising one or more polymer carriers and at least one pharmaceutically active substance, wherein a concentration of the pharmaceutically active substance varies in the longitudinal direction of the stent. Paragraph 34 of Sirhan is cited as providing "areas (e.g., distal and proximal ends of the device) having variable thickness of both the source and the rate-controlling element to allow for slower or faster release." Paragraph 135 of Sirhan (which describes the embodiment shown in Fig. 9) is also cited as providing variable delivery of a therapeutic substance. Furthermore, paragraphs 40 and 45-46 were cited as indicating that degradation behavior of the carrier can serve to differentiate the local elution characteristics. However, Sirhan provides different concentrations of a pharmaceutically active substance along the longitudinal direction of the stent by providing or omitting a coating that carries a pharmaceutically active substance. The Applicants find no teaching or suggestion of a variation in concentration *within the polymer carrier* in Sirhan. Instead, the coatings have a consistent concentration of a pharmaceutically active substance throughout their length.

Therefore, the Applicants maintain that independent claim 1, as amended, patentably distinguishes over Sirhan. Likewise, claims 2-5, which depend from and incorporate all the limitations of claim 1 also patentably distinguish over Sirhan. Claims 9-11 have been cancelled without prejudice or disclaimer as to the subject matter contained therein, making the rejection of these claims moot. Withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 1-5 also stand rejected as being anticipated by Wang. As with Sirhan, Wang also provides the delivery of different concentrations of a pharmaceutically active substance along the longitudinal direction of the stent by the presence or absence of a coating that contains a pharmaceutically active substance, not by a difference in concentration within the coating. For example, in paragraph 0044, Wang provides that the coating may be present on 1% - 40 % of the stent where only one end is coated, or 2% - 80% of the stent where two ends are coated. Additionally, Figs. 1 and 11 show coating 18 as only being present at the proximal and distal ends of the stent. The Applicants find no teaching or suggestion in Wang of a variation in concentration *within the polymer carrier* in the longitudinal direction.

Therefore, the Applicants maintain that independent claim 1, as amended, patentably distinguishes over Wang. Likewise, claims 2-5, which depend from and incorporate all the limitations of claim 1 also patentably distinguish over Wang. Withdrawal of the rejection of claims 1-5 under 35 U.S.C. § 102(b) and the issuance of a Notice of Allowance is respectfully requested.

The outstanding Office action was transmitted on 29 May 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. No extension of time or accompanying fee is believed to be due in making this response. Nevertheless, the Applicants hereby make a conditional petition for an extension of time for response in the event that such a petition is required. No fees are believed to be due with this response. However, in the event that a fee for the filing of his response is insufficient, the Commissioner

is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

/John J. Cunniff/

Hahn Loeser & Parks LLP  
One GOJO Plaza, Suite 300  
Akron, OH 44311  
330-864-5550  
Fax 330-864-7986

John J. Cunniff  
Reg. No. 42,451

[jcunniff@hahnlaw.com](mailto:jcunniff@hahnlaw.com)